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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/869,949	08/06/2001	Teruo Nishida	01398/HG	4424

1933 7590 10/06/2004

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EXAMINER

FAY, ZOHREH A

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 10/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/869,949

Applicant(s)

NISHIDA ET AL.

Examiner

Zohreh Fay

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

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Claims 1-18 are presented for examination.

The remarks filed on January 6, 2004 have been received and entered.

Claims 1-18 are rejected under 35 U.S.C. 112 first paragraph for the reasons set forth on page 2 of the office action of October 8, 2003.

Claims 1-18 are rejected under 35 U.S.C. 102 (b) for the reasons set forth on page 2 of the office action of March 27, 2003.

Applicant's arguments and remarks regarding the 112 first paragraph have been carefully considered but are not deemed to be persuasive. The following precedent is believed relevant to the instant case.

Regents of the University of California v. Eli Lilly & Co., 119 F.3d 1559, 1968 (Fed. Cir. 1997), cert. Denied, 523 U.S. 1089, 118 S.Ct. 1548 (1998), hold that an adequate written description requires a precise definition, such as by structure, formula, chemical name, or physical properties, "not a mere wish or plan for obtaining the claimed chemical invention." Eli Lilly, 119 F. 3d at 1566. The Federal Circuit has adopted the standard set forth in the Patent and Trademark Office ("PTO") guidelines for Examination of Patent Applications under the 35 U.S.C. 112. "Written Description" requirement ("Guidelines"). 66 Fed Reg. 1099 (Jan.5, 2001), which state that the written description requirement can be met by "showing that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics,"including, inter alia' functional characteristics when coupled with a known or disclosed correlation between function and structure "Enzo biochem, inc.v.Gen-probe inc., 296 F.3d, 316, 1324-25 (Fed. Cir 2002) (quoting guideline, 66 Fed. Reg. At 1106 (emphasis added.

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Moreover, although Eli Lilly and Enzo were decided within the factual context of DNA sequences, this does not preclude extending the reasoning of those cases to chemical structure in general. Univ. of Rochester V. G.D. searle & co., 249 F.supp.2d 216, 225 (W.D.N.Y. 2003).

The instant claims generally recite the use of a compound having an effect on activating Rho. When functional claims are drawn this broadly, they are inclusive of any compound having an effect on activating Rho, which can be small molecules, peptides, peptide mimetics or RNA-DNA based structures. The instant specification quite simply, discloses a few compounds within the scope of the claimed language. As such, it cannot possibly provide any direction for using any peptides, peptide mimetics, or RNA-DNA based structure; no identifying characteristics of any kind, e.g. sequences, are provided. Accordingly, the instant specification fails to provide an adequate written description.

Applicant's arguments regarding the 102 (b) rejection are not also deemed to be persuasive. Liliom et al. clearly teach the use of LPA for the promoting cellular regeneration of the injured cornea. Such teaching indicates the use of the claimed compounds for the cellular regeneration of cornea in general. There is no evidence of record to demonstrate that the treatment of corneal injury is determined based on the cells involved in such injury, and can be different for each cell type.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zohreh Fay whose telephone number is (571) 272-0573. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Z.F

EXAMINER
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GROUP 1200

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